

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0311]

JMB

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**Medical Devices: Draft Guidance on "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA;" Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA." This draft guidance document will serve as the special control for reclassification of the endolymphatic shunt tube with valve device from class III to class II. The draft guidance document outlines the technical areas to address in order to control the risks associated with the endolymphatic shunt tube with valve and to provide for a timely premarket notification (510(k)) review. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing you request, or fax your request to 301-443-8818. Submit written comments

concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** James K. Kane, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA." The draft guidance document is the special control guidance for the endolymphatic shunt tube with valve. Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify the device from class III to class II when it is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's Disease. FDA intends that this draft guidance document, if finalized, will serve as the special control for the endolymphatic shunt tube with valve. If finalized, the guidance will supersede the guidance document entitled "Guidance for the Technical Content of a Premarket Approval Application for an Endolymphatic Shunt Tube With Valve" that FDA issued in April 1990.

##### **II. Significance of Guidance**

The draft guidance represents the agency's current thinking on the endolymphatic shunt tube with valve. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

### III. Electronic Access

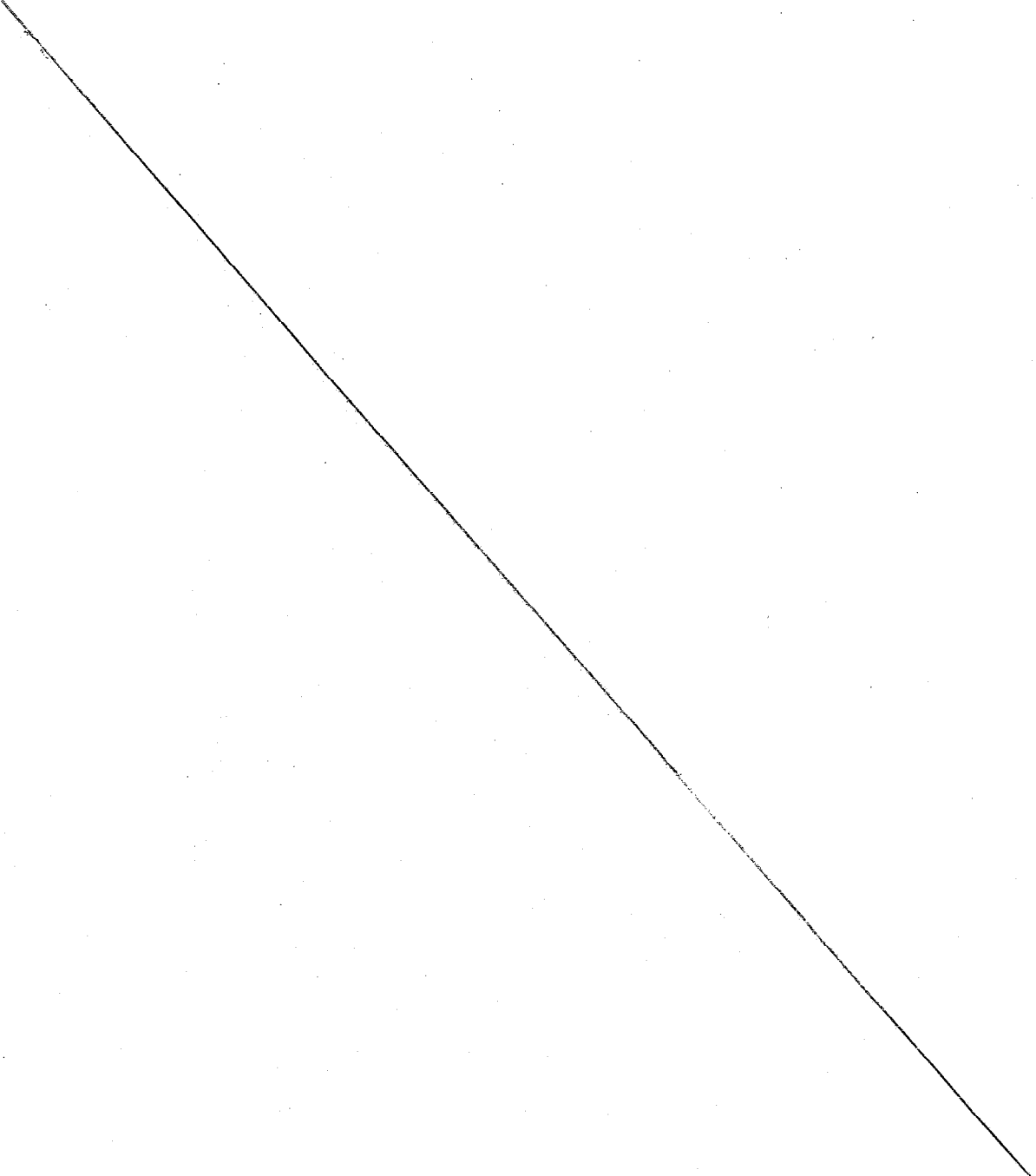
In order to receive "Class II Special Control Guidance Document: Endolymphatic Shunt Tube With Valve; Draft Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter document number 791 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

### IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals

may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 8/2/01

August 2, 2001.

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